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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/942,098

08/28/2001

Lance E. Steward

17451 (BOT)

6185

51957

7590

09/07/2006

ALLERGAN, INC., LEGAL DEPARTMENT
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599

EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,098

Applicant(s)

STEWART ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8,45-49,51-53,55,57-63,96-122,126-146,149-168 and 170-211 is/are pending in the application.
- 4a) Of the above claim(s) 7,133,198,199,204 and 205 is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) 102-109,116 and 117 is/are rejected.
- 7) ☒ Claim(s) 110-122,155-159 and 176-195 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>6/14/06</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed June 22, 2006 is acknowledged and has been entered. Claims 1-3, 9-44, 50, 54, 56, 64-95, 123-125, 147, 148 and 169 have been canceled. Claims 4-8, 45-49, 51-53, 55, 57-63, 96-122, 126-146, 149-168 and 170-178 have been amended. New claims 179-211 have been added. Claims 4-6, 8, 45-49, 51-53, 55, 57-63, 96-122, 126-132, 134-146, 179-197, 200-203 and 206-211 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 7, 133, 198, 199, 204 and 205 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 17, 2006.

5. Claim 116 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites

“DANCYL”; there is no recitation of this term found in the specification. Does Applicant mean DABCYL?

6. Claims 102-109 are rejected under 35 U.S.C. 102(e) as being anticipated by Schmidt et al 6762280.

Schmidt et al discloses substrates for clostridial neurotoxins and that these substrates can be modified peptides or proteins that can serve as FRET substrates (abstract; col. 4). Schmidt et al discloses that Botulinum serotype A cleaves the protein SNAP-25 and that because botulinum neurotoxins are proteases, practical assays for this activity could form the basis for detection, quantification and drug-screening systems (col. 1). Schmidt et al discloses substrate peptides suitable for use in fluorescence resonant energy transfer assays (FRET), also known as quenched-signal assays, for the protease activities of clostridial neurotoxins (col. 3). Schmidt et al discloses “FRET substrates for proteolytic activities of clostridial neurotoxins. Each contains a fluorescent group (fluorophore) on one side of the cleavage site, and a molecule that quenches that fluorescence on the other side of the cleavage site. Upon neurotoxin-catalyzed hydrolysis, the fluorophore and quencher diffuse away from each other, and the fluorescence signal increases in proportion to the extent of hydrolysis.” (col. 5; see also col. 7). The amino acid sequences set forth in pending claims 102-104 are in Schmidt et al (see Schmidt et al SEQ ID NO: 11 and 12). The human SNAP-25 sequence is disclosed in Schmidt et al. The prior art anticipates the claimed invention. It is noted that none of these claims recite how many amino acids should separate the donor fluorophore from said acceptor.

The rejection is maintained for the reasons of record. Applicants have argued (6/22/06 amendment) that the BoNT/A substrate of Claim 102 and the claims depending from this independent claim recite, in part, a BoNT/A substrate comprising "a donor fluorophore" and "an acceptor." The peptide substrates SEQ ID NO: 11 and SEQ ID NO: 12 only have one fluorophore located at position 1 of both substrates. Thus, the peptides of SEQ ID NO: 11 and SEQ ID NO: 12 of the Schmidt patent do not read on Claims 102-112 and 118-122. It is noted that the rejection is maintained for only claims 102-109. Further, it is noted that claim 102 only recites one fluorophore, a donor fluorophore.

7. Claim 117 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a trademark item. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

8. Claim 114 is objected to because of the following informalities: there is not a period at the end of the sentence. Appropriate correction is required.

9. Claims 110-1122, 155-159, 176-196 are objected to because they depend from a rejected claim.

10. Claims 4-6, 8, 45-49, 51-53, 55, 57-63, 96-101, 126-132, 134-146, 149-154, 160-168, 170-175, 196-197, 200-203 and 206-211 are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

September 5, 2006

Continuation of Disposition of Claims: Claims allowed are 4-6,8,45-49,51-53,55,57-63,96-101,126-132,134-146,149-154,160-168,170-175,196,197,200-203 and 206-211.